IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IN RE: TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	C.A. No. 05-340 KAJ
THIS DOCUMENT RELATES TO: C.A. No. 05-340 KAJ (Louisiana Wholesale) C.A. No. 05-351 KAJ (Rochester Drug) C.A. No. 05-358 KAJ (Meijer, Inc., et al.)	Hon. Kent Jordan, U.S.D.J.

DIRECT PURCHASER CLASS PLAINTIFFS' FIRST AMENDED AND CONSOLIDATED CLASS ACTION COMPLAINT

Direct Purchaser Plaintiffs, Louisiana Wholesale Drug Company, Inc. ("LWD"), Rochester Drug Co-Operative, Inc. ("RDC") and Meijer, Inc. and Meijer Distribution, Inc. (collectively "Plaintiffs") on behalf of themselves and all others similarly situated, for their First Amended and Consolidated Class Action Complaint ("Amended Complaint") against defendants Abbott Laboratories ("Abbott"), and Fournier Industrie et Santé, and Laboratories Fournier S.A. (jointly "Fournier") (collectively "Defendants"), allege as follows based on: (a) personal knowledge; (b) the investigation of their counsel, including review of various pleadings and court orders in patent infringement litigation pending in this district; and (c) information and belief:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of Defendants' unlawful exclusion of competition from the market for fenofibrate, a drug used to control levels of cholesterol and triglycerides in humans, manufactured and sold by Defendants under the brand-name

TriCor. As alleged below, Defendants used various acts and practices as part of an overall scheme to improperly maintain and extend Defendants' monopoly power in the market for fenofibrate, to the detriment of Plaintiffs and the Class (as defined below).

2. Defendants began marketing a capsule version of their brand name drug TriCor in 1998. Defendants quickly garnered substantial revenues from the sale of TriCor capsules, generating over $227 million in revenues in 2001. Defendants, however, recognized the substantial threat to their monopoly profits posed by the potential onset of competition from generic versions of TriCor. Since generics are generally priced significantly below the brand-name drug, such products typically take the vast majority of the brand-name version's sales directly and quickly after their introduction into the marketplace.

3. In response to the serious competitive threat posed by generics, Defendants concocted a multifaceted scheme, executed over the course of several years, to maintain and extend their monopoly power in the fenofibrate market by improperly preventing generic manufacturers from effectively competing with Tricor. Defendants' scheme was executed through a purposeful and planned manipulation of the complex distribution system for pharmaceutical products in the U.S., as well as the courts, the patent laws, and the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetics Act (21 U.S.C. § 301-392) ("Hatch-Waxman").

A. The First Conversion

4. Fearing the onset of generic competition, on November 10, 1999, Defendants applied to the U.S. Food and Drug Administration ("FDA") for approval to market a tablet version of TriCor, which was therapeutically equivalent and bioequivalent to the TriCor capsules that Defendants were

marketing at the time. This tablet formulation offered no medical/clinical benefits over the existing capsules. Defendants nonetheless expended significant resources developing and seeking FDA approval for their tablet formulation, in order to use that new formulation as part of a scheme to exclude and minimize generic competition.

5. As part of their scheme to exclude generic competition, Defendants took affirmative steps to (a) destroy the pre-existing demand for fenofibrate capsules, and (b) shift that demand to Defendants' tablet formulation (since there were no pending tablet ANDAs). This scheme was executed through, inter alia, the following acts:

a. Defendants purposely and intentionally sought to convert all TriCor prescriptions from the existing capsule formulation to the tablet formulation by, inter alia, instructing representatives to promote only the tablet formulation, while discouraging physicians from writing prescriptions for the older capsule formulation.

b. In order to give themselves time to carry out this conversion process, Defendants brought sham patent infringement suits in the Illinois District Court against the generic manufacturers. Defendants thereby took advantage of the Hatch-Waxman regulatory framework governing the marketing of generic drugs, which requires the FDA to stay approval of such drugs for up to 30 months when patent claims are asserted, regardless of the objective and subjective baselessness of such suits.

c. Defendants also took active steps to destroy any demand for the old capsule formulation that might have continued to exist despite Defendants' sales tactics. For example, Defendants removed the capsule formulation from the National Drug Data File, thereby impeding

generic substitution for any prescriptions written for the branded capsule formulation. In addition, once Defendants' market conversion strategy had succeeded, Defendants took steps to ensure that the branded capsule formulation would be unavailable in the marketplace, ensuring that patients on Tricor would be compelled to switch to the new formulation.

6. As a result of Defendants' conduct, by the time generic manufacturers were able to start selling their generic capsule versions of fenofibrate, the demand for fenofibrate capsules had been switched to the TriCor brand fenofibrate tablets. Moreover, because capsules constitute a different dosage form than tablets (and had different dosage strengths), pharmacists and others could not legally substitute generic capsules for prescriptions which had been converted to Defendants' tablet formulation, even though the capsule and tablet products were therapeutically equivalent and bioequivalent.

7. Defendants were able to almost completely shift the demand for fenofibrate from the capsules to the tablets before April 2002, when the first generic fenofibrate capsules came to market, thereby precluding the generic manufacturers from effectively competing with Defendants. In fact, even though generic equivalents typically capture well over 50% of the sales of their branded counterpart in their first year on the market, Defendants' scheme caused Teva, the first manufacturer of generic fenofibrate capsules to come to market, to capture only **5%** of the fenofibrate market.

B. <u>The Second Conversion</u>

8. Defendants' greed was not satiated by the success of their first illegal, exclusionary conversion. As Defendants knew, after Defendants obtained FDA approval for their fenofibrate tablet New Drug Application ("NDA"), Teva and generic manufacturer Impax Laboratories, Inc.

("Impax") began developing generic versions of that formulation. As a result, Defendants took active steps to once again change the formulation of their TriCor tablets, and convert the demand for fenofibrate to that second tablet formulation, before the generic manufacturers could obtain FDA approval to sell generic versions of the first tablet formulation.

9. Upon receiving notice of Teva's and Impax's tablet ANDAs, Defendants again blocked the generic competitors by reflexively filing patent infringement suits, this time before this Court, without regard to whether those suits had any merit. These suits were based on multiple patents which Defendants had obtained during the additional period of market dominance that the capsule-to-tablet conversion scheme had afforded them, and triggered multiple 30-month stays of approval of Teva's and Impax's proposed generic tablets. Meanwhile, with these suits ongoing, Defendants sought and obtained FDA approval to market their second tablet formulation. Due to the success of their continuing exclusionary scheme, Defendants were able to again convert the market from (a) Defendants' pre-existing product (i.e. the first tablet formulation), which faced immediate generic competition; to (b) Defendants' second tablet formulation, before generic versions of the first tablet formulation could enter the market. The second tablet formulation (a) offered minimal (if any) benefits over the capsules or the first tablet formulation, and (b) any supposed benefits from the second tablet formulation were far outweighed by the increased cost of the new branded product relative to the prospective generic competitors. However, because the second tablet formulation had different dosage strengths than the first tablet formulation, and therefore was not AB-rated to (and thereby substitutable for) the first formulation, this new formulation protected Defendants from imminent competition from generic versions of the first tablets. And after having

again successfully carried out a conversion from an existing formulation which faced imminent generic competition to a new formulation, Defendants once more poisoned the marketplace for generic entrants seeking to sell the existing formulation, and even drained the existing (first tablet) formulation from the pharmaceutical distribution channel altogether.

10. If Defendants were simply and solely interested in introducing a new TriCor product which was supposedly superior to existing formulations of fenofibrate, they could have done so without taking the additional, affirmative steps described above to prevent generic versions of the prior formulation from being sold. That Defendants took such affirmative steps reflects that their goal, as clearly stated in their own internal documents, was not to promote consumer welfare, but to stymie generic competition and preserve their own monopoly power. That Defendants' ongoing scheme has successfully stymied competition from generic fenofibrate is reflected in the fact that, despite the generic manufacturers' efforts to seek and obtain FDA approval for generic versions of fenofibrate, as of year end 2004, Defendants maintained control of 95% of the fenofibrate sales in the United States, receiving over $750 million in revenues.

11. As a result of their illegal scheme, Defendants: (1) illegally maintained and extended their monopoly in the market for fenofibrate in the United States; (2) fixed, raised, maintained, and/or stabilized the price of fenofibrate at supra-competitive levels; and (3) overcharged Plaintiffs and other direct purchasers of TriCor from Defendants by millions of dollars by depriving them of the benefits of competition from cheaper generic versions of TriCor.

12. Defendants' monopoly power, as described above, was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a legally

obtained valid patent, other legally obtained market exclusivity, a superior product, business acumen or historic accident.

13. As alleged in more detail below, Defendants violated § 1 and § 2 of the Sherman Act through their conspiracy to engage in an overarching scheme to improperly maintain and extend their market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of TriCor. Furthermore, on information and belief, Defendants' conspiracy continues in effect and, unless remedied through injunctive relief, will continue to restrain competition in the market for fenofibrate.

II. JURISDICTION AND VENUE

14. This Complaint is filed and these proceedings are instituted under sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15(a) and 26, to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiffs and members of the Class of direct purchasers of TriCor from Defendants (defined below) resulting from violations by the Defendants, as hereinafter alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1- 2, and for injunctive relief. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

15. Defendants transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

16. Plaintiff LWD is a corporation organized under the laws of the State of Louisiana and is located at 2085 I-49 South Service Road, Sunset, Louisiana 70584. LWD purchased TriCor directly from Abbott during the Class Period as defined below, and was injured by the illegal conduct described herein.

17. Plaintiff RDC is a drug wholesale cooperative located at 50 Jet View Drive, Rochester, New York, 14624. RDC purchased TriCor directly from Abbott during the Class Period as defined below, and was injured by the illegal conduct described herein.

18. Plaintiffs Mejier Inc. and Meijer Distribution, Inc. (collectively "Meijer") are corporations organized under the laws of the State of Michigan, with their principal places of business in Grand Rapids, Michigan. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the Class Period, as defined below, purchased TriCor directly from Abbott.

19. Defendant Abbott is a company incorporated under the laws of the State of Illinois, with its principal place of business in Abbott Park, Illinois. Abbott develops, manufactures, and markets pharmaceuticals and related products in the United States.

20. Defendants Fournier Industrie et Santé, formerly known as Fournier Innovation et Synergie, and Laboratories Fournier, S.A. are French corporations, with their principal places of business at 42 Rue de Longvie, 21300 Chenôve, France.

IV. CLASS ACTION ALLEGATIONS

21. Plaintiffs bring this action on behalf of themselves and, under Rules 23(a),(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

> All persons or entities in the United States who purchased TriCor in any form directly from any of the Defendants at any time during the period April 9, 2002, through the present (the "Class").

Excluded from the Class are Defendants, and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

22. Injunctive relief is appropriate under Rule 23(b)(2) because, as alleged herein, Defendants have acted on grounds generally applicable to the class, thereby making appropriate final injunctive relief with respect to the class as a whole.

23. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe the Class numbers in the hundreds. Further, the Class is readily identifiable from information and records in the possession of Defendants.

24. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for fenofibrate and were deprived of the benefits of competition from cheaper generic versions of TriCor as a result of Defendants' wrongful conduct.

25. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

26. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

27. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on

grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

28. Questions of law and fact common to the Class include:

a. whether Defendants maintained monopoly power by delaying generic entry;

b. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

c. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

d. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

e. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class, and if so, the appropriate measure of damages.

29. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

30. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTUAL ALLEGATIONS

A. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand-Name Drugs Are Approved

31. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301-392), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

32. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

33. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

34. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand-name drug.

35. As a counter-balance to this abbreviated process for bio-equivalent generic drugs, Hatch-Waxman streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions (as detailed below), the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand-name drug for up to 30 months.

36. When the FDA approves a brand-name manufacturer's NDA, the FDA publishes any compound patents which (according to the brand-name manufacturer) claim the approved drug in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. §355(j)(7)(A)(iii). In the case of method of use patents, the FDA lists in the Orange Book any patents which (according to the brand-name manufacturer) claim the approved drug for its approved method of use. In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand-name manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand-name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand-name manufacturer similarly certifies, inter alia, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents).

37. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand-name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand-name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

38. If a generic manufacturer files paragraph I or II certifications, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A). If a generic manufacturer files a paragraph III certification, then the FDA can go forward with the ANDA approval process but "final approval" cannot be granted until expiration of the applicable patent(s).

39. If a generic manufacturer files a Paragraph IV certification claiming that a patent listed in the Orange Book is invalid or will not be infringed, a brand-name manufacturer has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market. When a generic drug manufacturer files a paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand-name drug manufacturer may delay when the generic drug is finally approved by the FDA, and when generic competition to the brand-name drug enters the market. During the pendency of the 30 month stay,

the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay.

40. Because of the FDA rules alleged above, brand-name manufacturers have an incentive to: (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) then sue any *generic competitor* that files an ANDA with paragraph IV certifications, even if such competitor's product does not actually infringe the listed patent(s) (or even if such patents are invalid or otherwise unenforceable) in order to delay final FDA approval of an ANDA for up to 30 months. In addition, prior to a recent change in the Hatch-Waxman regulations, brand companies could, and did, bring multiple infringement suits (based on multiple patents listed in the Orange Book) against a single ANDA, thereby obtaining independent 30-months stays associated with each suit. This practice was curtailed by a change in FDA regulations mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which, due to repeated abuses by brand manufacturers of the type described here, limited brand manufacturers to a single stay per ANDA. See 21 C.F.R. §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

B. Generic Versions of Brand-Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand-Name Versions

41. Typically, generic versions of brand-name drugs are priced significantly below the brand-name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand-name counterparts. In particular, generic drugs that are bioequivalent to their brand name counterparts are given an "AB" rating by the FDA. In every state, pharmacists are permitted (and, in some states, required) to substitute an AB-rated generic product for a brand-name product unless

the doctor has indicated that the prescription for the brand-name product must be dispensed as written. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generic accelerates. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand-name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers have a strong interest to use the tactics alleged above to delay the introduction of generic competition into the market.

C. TriCor

42. TriCor is used to reduce high-levels of low-density lipoprotein cholesterol ("LDL-C"), sometimes referred to as "bad cholesterol," and triglycerides by promoting the dissolution and elimination of fat particles in the blood. TriCor also increases levels of high-density lipoprotein cholesterol ("HDL-C"), sometimes referred to as "good cholesterol," and reduces LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad cholesterol and high triglycerides). TriCor is also effective at reducing triglycerides in patients with hypertriglyceridemia (high triglycerides). The active pharmaceutical ingredient in TriCor is *fenofibrate*.

43. Fenofibrate is a fibrate. Fibrates, statins, bile acid sequestrants, and niacin are categories of cholesterol-lowering drugs. Each of those categories addresses cholesterol conditions differently, each has different side effects, some more serious than others, and each has different efficacy profiles in (i) reducing LDL-C, (ii) raising HDL-C, and (iii) lowering triglycerides. A cholesterol-lowering drug from any of the four categories is not reasonably interchangeable with a drug from another of the categories.

44. Fibrate drugs include TriCor (fenofibrate), Atromid (clofibrate), and Lopid (gemfibrozil). Each fibrate drug is approved by the FDA for different indications, has different side effects, and is prescribed in specific and different circumstances that depend on the particular condition of the patient.

45. Because of the wide variations in side effects associated with clofibrate, gemfibrozil, and fenofibrate, differences in their approved indications, differences in how they are ingested, and other differences, including those relating to their prescription and efficacy profiles, the three types of fibrate drugs are not reasonably interchangeable. Furthermore, according to Defendants' own internal documents, TriCor is the sole occupant of a unique "niche," differentiated from other drugs used to control cholesterol and triglyicerides by virtue of its unique efficacy in controlling both levels of HDL and LDL cholesterol, as well as triglycerides.

D. Defendants' Wrongful Scheme to Delay Generic Competition

46. In 1997, Fournier granted Abbott an exclusive license to a patent (the '726 patent, as defined below) in the United States covering a formulation of fenofibrate. Defendants submitted separate NDAs for three strengths of branded fenofibrate capsules it intended to market. The FDA

approved the TriCor 67mg capsule NDA on February 9, 1998, and the TriCor 134 mg and 200 mg capsule NDAs on June 30, 1999. Defendants brought each of these capsule products (collectively, "TriCor A") to market shortly after receiving FDA approval, and sales of the capsule rose quickly to top $158 million by 2000, and $277 million in 2001.

1. The First Exclusionary Conversion

47. Defendants realized that these tremendous profits could only be sustained for as long as they could retain their monopoly share of the fenofibrate market. Defendants also well knew, from the time they launched TriCor A, that: (a) generic manufacturers such as Teva Pharmaceuticals, Inc. ("Teva") and Impax Laboratories, Inc. ("Impax") might seek to develop AB-rated generic versions of TriCor A; and (b) an AB-rated generic product typically captures from 40% to 80% (or more) of the brand's sales within the first year of launch.

48. To stave off this threat, Defendants hatched a scheme to act together to prevent generic manufacturers from effectively competing with TriCor, which scheme included: (a) filing baseless lawsuits which Defendants knew would preclude generic manufacturers from obtaining FDA approval for up to 30 months; (b) using that period of delay to develop tablet formulations of TriCor that provided the same medical or clinical benefits as TriCor A, but purposefully were made in different dosage forms and strengths in order to ensure that they would not be AB-rated to TriCor A; (c) listing TriCor A as "obsolete" in a publication used by pharmacies to determine substitutability of brand and generic drugs, in order to prevent such substitution in the case of TriCor, and (d) taking various steps (such as "bleeding down" its capsule inventory) to force patients to

switch to the tablet formulation before generics could enter the market with their generic capsule formulations.

49. As a result of this exclusionary scheme, Teva and Impax were denied the opportunity to effectively launch their generic capsule products, and were excluded from the most efficient means of distributing their products. And, as Defendants acknowledge in their own internal documents, when Teva was finally able to launch its fenofibrate capsule (which remained bioequivalent to the TriCor tablet formulation, but was much less expensive), Teva captured only 5% of the fenofibrate market, as opposed to the 40–80% or more that generic versions of brand name drugs, under unfettered market conditions, would normally capture.

50. This scheme was executed through a number of interrelated steps, which exploited the courts, the Hatch-Waxman regulatory scheme, and characteristics of the pharmaceutical distribution system:

(a). The Curtet ('726) Patent

51. As a non-polar molecule, fenofibrate has limited solubility in polar solvents such as water and other aqueous (i.e., water-based) media. Further, to the extent it is soluble in polar solvents, fenofibrate dissolves slowly relative to more polar molecules. As a result, the rate and extent of dissolution of fenofibrate in the human digestive tract, which is composed largely of water, is limited.

52. On January 19, 1989, Fournier filed a patent application that issued as United States Patent No. 4,895,726 ("the Curtet Patent" or "'726 Patent") on January 23, 1990.

53. The Curtet Patent is titled "Novel Dosage Form of Fenofibrate." It states that "[i]t is known . . . that the bioavailability of fenofibrate is not equal to 100%" and discloses a *fenofibrate* composition designed to exhibit "improved bioavailability." See Curtet Patent at 1:5–8.

54. The Curtet Patent has two independent claims, Claims 1 and 10, which recite "a co-micronized mixture of particles of fenofibrate and a solid surfactant" and "co-micronization of the fenofibrate and a solid surfactant," respectively:

> (Claim 1) A therapeutic composition, which is presented in the form of gelatin capsules and which is useful especially in the oral treatment of hyperlipidemia and hypercholesterolemia, said composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant, wherein the mean particle size of said co-micronized mixture is less than 15 μm.
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> * * *
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> (Claim 10) A method for improving the bioavailability of fenofibrate in vivo, which comprises co-micronization of the fenofibrate and a solid surfactant, the said co-micronization being carried out by micronization of a fenofibrate/solid surfactant mixture until the particle size of the powder obtained is less than 15 μm.

See id. at 5:6–13 and 6:20–25 (emphasis added). Each of the remaining claims depends from either Claim 1 or Claim 10. Thus, these claims require, respectively, "a co-micronized mixture" and the step of "co-micronization of the fenofibrate and a solid surfactant." Each of the remaining claims depends from either Claim 1 or Claim 10 and can be infringed only if Claim 1 or Claim 10 is infringed.

55. The specification of the Curtet Patent acknowledges that it was previously "known" that improved bioavailability could be achieved by micronizing drug substances and/or by adding a surfactant:

> It is known that the micronization of an active principle is capable of improving the dissolution of the said active principle in vivo, and hence its bioavailability. It is also known that the addition of a surfactant excipient to a formulation of an active principle is capable of improving the absorption and consequently the bioavailability of the said active principle.

See id. at 1:28–34.

56. According to the Curtet Patent, its inventors discovered a significant benefit could be achieved by co-micronizing fenofibrate and a solid surfactant, which is explicitly defined in the Curtet Patent as "the micronization of an intimate mixture of fenofibrate and a solid surfactant." See id. at 1:35–38 (emphasis added). The Curtet Patent distinguishes products obtained through co-micronization from, among others, products obtained by "micronizing the fenofibrate on its own." See id. at 1:35–43. For these and other reasons, the specification of the Curtet Patent thus makes clear that the co-micronization limitation requires that fenofibrate and a solid surfactant be mixed together and then micronized as an "intimate" mixture that excludes other components.

57. In the accompanying remarks, Fournier explained the basis for the amendment, making clear that co-micronization required micronization of a "mixture" of fenofibrate and the solid surfactant: "none of the [cited] references alone or in any combination thereof teaches or suggests…that by co-micronizing said mixture a lower daily dosage may be administered because the bioavailability of fenofibrate is significantly and unexpectedly increased." See id. Thus, the amendment clarified that the claimed co-micronization was performed on a mixture of fenofibrate and solid surfactant, not on the fenofibrate alone.

58. Fournier's other remarks also made this point explicitly by contrasting the relative dissolution rates of the claimed formulations from formulations in which the fenofibrate was micronized by itself and then mixed with the solid surfactant:

> [It can] be seen in all instances fenofibrate in the co-micronized mixture dissolves about 20-25% faster than fenofibrate that is micronized prior to mixing with micronized solid surfactant . . . . none of [the cited references] teach or suggest that co-micronizing fenofibrate with a solid surfactant will increase the rate at which fenofibrate dissolves compared to the rate at which micronized fenofibrate mixed with micronized solid surfactant dissolves. . . .

See id. at 3. Based in whole or in part on these arguments and representations, the Examiner ultimately withdrew his prior art rejections.

59. The prosecution history of the Curtet Patent further buttresses the conclusion dictated by the specification.

60. In December 1999, Fournier filed for reexamination of the Curtet Patent. In the reexamination, Fournier continued its theme that co-micronization was limited to the micronization of a mixture of fenofibrate and solid surfactant: "[U]nlike fenofibrate which exhibits unexpectedly rapid dissolution when co-micronized with surfactant compared with fenofibrate micronized alone, [other fibrates] show no statistically significant increase in dissolution." See id. at 5. To further distinguish the claimed co-micronized products from products in which fenofibrate was micronized alone, Fournier submitted a declaration by inventor Philippe Reginault that compared "co-micronized fibrates" with "the corresponding fibrate that was first micronized and then mixed with a micronized solid surfactant." See id. at 5–6.

61. Thus, the Curtet Patent claims, specification, original prosecution history and reexamination prosecution history clearly compel a conclusion that the claims are limited to

fenofibrate formulations in which the co-miconization step is performed on a mixture of fenofibrate and solid surfactant without the presence of additional excipients. No patent attorney could reasonably take a position to the contrary.

(b). The Illinois Patent Litigation

62. On December 14, 1999, Novopharm Limited (which was subsequently acquired by Teva) filed an ANDA with the FDA requesting approval to market generic fenofibrate 67 mg capsules (the "Teva Capsule ANDA") before the expiration of the '726 Patent. The Teva Capsule ANDA was later amended by Novopharm to request approval to market generic fenofibrate 134 mg and 200 mg capsules (all the formulations included in "TriCor A"). In connection with the Teva Capsule ANDA, Novopharm certified under Paragraph IV that the proposed generic fenofibrate capsule did not infringe the '726 Patent.

63. On May 9, 2000, Impax also filed an ANDA for TriCor A. Impax similarly sought approval to market its fenofibrate capsules prior to the expiration of the '726 Patent, and accordingly certified under Paragraph IV that its product did not infringe the '726 Patent, and duly and timely notified Abbott of its ANDA.

64. The generic fenofibrate capsules covered by the Teva Capsule ANDA and Impax Capsule ANDA are not made using co-micronization, as required by the '726 Patent claims. For example, under Teva's process, fenofibrate is "first pre-micronized on its own and in the absence of any other ingredient. The pre-micronized fenofibrate is then dry mixed with lactose monohydrate, pregelatinized starch, croscarmellose sodium and crosspovidone." Abbott Laboratories v. Novopharm Ltd., 2002 WL 433584, *3 (N.D.Ill. Mar 20, 2002). Solid surfactant is not used.

Instead, povidone and sodium lauryl-sulfate (i.e., the surfactant) are "dissolved in water to form a granulating solution. The granulating solution is then added to the dry fenofibrate mixture." See id. The mixture of the granulating solution and the dry fenofibrate mixture is then subjected to a wet granulation process involving the addition of more water and thorough mixing. See id. Following wet granulation, the mixture is dried. See id. This dried, granulated mixture is then dry blended with additional excipients to produce granules that can pass through a #16 mesh screen. See id. The granulated mixture is then blended again, weighed, and stored for eventual encapsulation into gelatin capsules. See id.

65. Despite these clear differences between the proposed generic products and the claims of the Curtet Patent, on or about April 7, 2000, August 18, 2000 and March 19, 2001, respectively, Defendants initiated a series of infringement actions in the United States District Court for the Northern District of Illinois, against Teva (and its subsidiary, Novopharm) and Impax, alleging that the generic drug manufacturers had infringed the '726 patent under 35 U.S.C. §271(e)(2) (these suits, collectively, referred to as the "Illinois Patent Litigation").

66. Under Hatch Waxman, these suits imposed 30-month stays on FDA approval of Teva's and Impax's generic products. Defendants knew that by merely filing the Illinois Patent Litigation within 45 days of receiving notice of the ANDA filings from Teva and Impax, Defendants would obtain the benefit of this delay, even though, as Defendants knew, the patent suits lacked merit.

67. The FDA granted Impax tentative approval for Impax's fenofibrate capsules on February 20, 2002. However, Abbott's and Fournier's lawsuit triggered the automatic 30-month stay under Hatch-Waxman, preventing FDA from granting final approval to Impax's capsule ANDA.

68. On March 19, 2002, the Illinois district court granted Teva's motion for summary judgment of non-infringement of the '726 Patent in the Illinois Patent Litigation. In so doing, the Court construed various elements of the '726 Patent, and concluded that Teva's generic fenofibrate capsule product did not literally infringe the terms of that patent. See Abbott Laboratories v. Novopharm Ltd., 2002 WL 433584 (N.D.Ill. Mar 20, 2002)

69. First, consistent with routine patent practice, the trial court construed the patent claims. Based on Fournier's statements in the patent, prosecution and reexamination proceeding, the district court unequivocally concluded that "the term 'co-micronized' is construed to mean that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients." See id. at *7. The court noted that, by distinguishing formulations in which fenofibrate was micronized by itself, Fournier disclaimed any coverage for such formulations:

> Plaintiff distinguishes its co-micronized mixture of fenofibrate and a solid surfactant from mixtures obtained by adding a surfactant to fenofibrate, or micronizing fenofibrate by itself, and/or mixing separately micronized fenofibrate and surfactant. By distinguishing its co-micronized mixture from these types of mixtures, Plaintiff's co-micronized mixture cannot include such mixtures. *See O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1581 (Fed. Cir. 1997).

See id. Elsewhere in its opinion, the trial court further stressed this point:

> During the prosecution of the Curtet Patent and the subsequent reexamination, Plaintiff repeatedly alleged that prior art did not teach or suggest co-micronization of a mixture of fenofibrate and a solid surfactant. Furthermore, Plaintiff stated that fenofibrate in the co-micronized mixture dissolves faster than fenofibrate dissolves when micronized fenofibrate is mixed with micronized solid surfactants. The

> prosecution history demonstrates that Plaintiff distinguished its claims, in part, on the fact that fenofibrate and a solid surfactant would be micronized together.

See id.

70. Consistent with the clear disclosure in the '726 Patent, the district court not only construed the co-micronization limitation to require the presence of both fenofibrate and solid surfactant in the co-micronization step, but also to require the absence of ingredients other than fenofibrate and solid surfactant. The court noted that both Claim 1 and Claim 10 involved co-micronization of a mixture and that "[n]o other materials or excipients are identified as being part of . . . these mixtures." See id. at *7. Further, the court noted that "[i]n all of the examples for preparing the product, fenofibrate and a solid surfactant are the only materials micronized together. After the co-micronization, other excipients are added." See id. The court summed its analysis as follows:

> The above demonstrates that Plaintiff micronizes together, fenofibrate and a solid surfactant. The claims, description, and prosecution history do not indicate that anything other than fenofibrate and a solid surfactant are micronized. Furthermore, the description and prosecution history indicate that one of the distinguishing elements of this Patent is the co-micronization of a fenofibrate/solid surfactant mixture. No other excipient is identified as part of this mixture one skilled in the art reading the claims, description, and prosecution history would conclude that the term "co-micronize" in claims 1 and 10 does not encompass co-micronization of excipients other than fenofibrate and a solid surfactant. Based on the above, the term "co-micronized" is construed to mean that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients.

See id. at *7 (emphasis added).

71. Based on the claim construction dictated by Fournier's lexicography and representations during prosecution, the district court concluded there was no genuine issue of material fact as to literal infringement:

> [T]he parties do not dispute that fenofibrate and a solid surfactant are not micronized together in the absence of other excipients in [Teva's] product. Accordingly, [Teva] does not literally infringe either claim 1 or claim 10 of the Curtet Patent.

See id. at *8. Thus, under the claim construction clearly mandated by the language of the '726 Patent, Abbott had no reasonable literal infringement position.

72. The district court also readily concluded that infringement under the doctrine of equivalents was precluded. The trial court noted that Fournier had not only narrowed the claims during prosecution, but expressly distinguished its claimed invention from products that employ micronization of fenofibrate alone or mixtures of individually micronized fenofibrate and surfactant. See id. at *8–9. The district court thus concluded that Fournier had surrendered equivalency for micronizing fenofibrate by itself or by mixing separately micronized fenofibrate and surfactant:

> Based on the arguments made during the prosecution of the patent as to increased bioavailability, patent language as to bioavailability, and the arguments made during reexamination, a competitor would reasonably conclude that Plaintiff relinquished a product and process that involved either adding a surfactant by itself or by micronizing the fenofibrate on its own or by intimately mixing the separately micronized fenofibrate and surfactant.

See id. at *9. Because Teva's product used the very process distinguished by Fournier—namely, micronizing fenofibrate by itself—the trial court concluded that Fournier "cannot establish infringement under the doctrine of equivalents for claims 1 or 10." See id. This result was compelled by settled patent law principles.

73. On March 20, 2003, a unanimous panel of the Federal Circuit Court of Appeals affirmed the district court's summary judgment. The Federal Circuit "disagree[d] . . . with [Abbott's] contention that the district court misconstrued the term 'co-micronization'" and affirmed

the district court's construction, in large part because Fournier "explicitly defined [that term] in the '726 patent specification":

> [T]he phrase "co-micronization of fenofibrate and a solid surfactant" is in fact explicitly defined at column 1, lines 35-38, of the '726 patent, as "micronization of an intimate mixture of fenofibrate and a solid surfactant." Hence, this is a case in which the patentee has "chosen to be his own lexicographer," and the district court did not err by reading the patentee's definition from the specification into the claim. Moreover, the inclusion of the word "intimate" in the definition, together with the fact that fenofibrate and SLS are the only ingredients present in every co-micronized mixture described in the '726 patent's specification, makes it **abundantly clear that** "co-micronization of . . . fenofibrate and a solid surfactant" should be construed as referring to co-micronization of a mixture consisting essentially of fenofibrate and solid surfactant.

Abbott Laboratories v. Novopharm Ltd., 323 F.3d 1324, 1330 (Fed. Cir. 2003) (emphasis added).

74. Like the district court, the Federal Circuit concluded that no issues of fact precluded summary judgment of non-infringement. Regarding literal infringement, the Federal Circuit stated: "Because it is undisputed that fenofibrate and a solid surfactant are not mixed in Novopharm's process without other significant ingredients, viz., excipients and water, being present, we conclude that there is no genuine issue of material fact as to literal infringement in this case." Id.

75. The Federal Circuit also deemed Abbott's theory of infringement under the doctrine of equivalents to be wrong "as a matter of law" and opined that adopting Abbott's theory would "contraven[e]" the well-established All Elements Rule:

> The process described in Novopharm's ANDA does not include any step in which fenofibrate and a solid surfactant are in a mixture in the absence of other excipients, and, in view of the above claim construction, **there can be no dispute that fenofibrate and solid surfactant are not "co-micronized" as that term is used in the '726 patent.** Significantly, Novopharm's process does not involve micronization of any mixture that includes fenofibrate and a solid surfactant, irrespective of the presence or absence of other excipients, as the SLS is dissolved in the aqueous granulating solution prior to mixing with the fenofibrate and remains in solution

> throughout the wet granulation and drying steps. Dissolved SLS is **clearly** not a "solid surfactant." Thus, even assuming that Novopharm's wet granulation and drying steps result in some reduction in fenofibrate particle size, those steps nonetheless cannot, as a **matter of law**, constitute co-micronization of an intimate mixture of fenofibrate and solid surfactant. **To hold otherwise would vitiate that limitation altogether, in contravention of the all-elements rule.** See Warner-Jenkinson, 520 U.S. at 39, n.8.

See id. at 1331 (emphasis added).

76. While the appeal before the Federal Circuit was pending, Teva received FDA approval to market its 67 mg, 134 mg and 200 mg capsules on April 9, 2002. Teva received final approval for its 134 mg and 200 mg capsules on this date, and came to market shortly thereafter. However, as a result of Defendants' exclusionary scheme (as detailed below), including Defendants' success in switching virtually all fenofibrate sales to tablets before generic manufacturers could get FDA approval of their capsule ANDAs, Teva's capsules were only able to capture a very small percentage of the sales of fenofibrate. The effect of the Illinois Patent Litigation was to provide Defendants with the necessary time to effect the switch to the tablets before generic capsules could capture a significant share of the fenofibrate market. Moreover, as a result of a change in FDA regulations regarding the application of the Hatch-Waxman mandatory 30-month stay, Teva received only tentative approval for its 67 mg capsule on April 19, 2002. Thus, as a result of the 30-month stay occasioned by Defendants' filing and prosecution of the baseless Illinois Patent Litigation, Teva was not able to launch its 67 mg capsule until September 3, 2002.

77. On March 26, 2003, the Illinois district court granted Impax's motion for summary judgment of non-infringement of the '726 Patent based, inter alia, on Impax's assertion of collateral estoppel on the basis of the earlier summary judgment that had been granted, and affirmed, in the

Teva infringement actions. The FDA subsequently granted Impax final FDA approval to market its fenofibrate capsule products on October 28, 2003.

(c). Defendants Execute the First Market Switch

78. As alleged above, Defendants knew that by merely filing the Illinois Patent Litigation within 45 days of receiving notice of the ANDA filings from Teva and Impax, they would, under the Hatch-Waxman regulatory framework, prevent the FDA from granting final approval to Teva and Impax for up to 30 months, regardless of whether Defendants' patent suits had any merit. Thus, even though Defendants knew that they would lose the Illinois Patent Litigation from the time it was filed, Defendants knew that by using the regulatory delay automatically triggered by the mere filing of those actions, they could delay competition from Teva's and Impax's generic TriCor A products for up to 30 months. This delay granted Defendants time to completely execute the market switch strategy they had devised to stifle generic competition, through a number of steps.

79. First, pursuant to a pre-conceived plan, Defendants began developing a tablet formulation of TriCor, in 54mg and 160mg strengths ("TriCor B"). From the outset, the purpose and effect of the plan to develop the tablets was not to provide the public with a better or improved product, but rather to protect Defendants' Tricor profits by thwarting, delaying and/or mitigating the impact of generic competition.

80. On September 4, 2001, Defendants obtained FDA approval to market TriCor B, while the Illinois Patent Litigation was still ongoing, and the 30 month stays of Teva's and Impax's generic fenofibrate capsules were still in effect. Importantly, these 54mg and 160mg strength tablets offered no benefits to consumers because they contained the same drug as the earlier-approved capsules and

were therapeutically equivalent and bioequivalent to the capsules. However, TriCor B offered huge benefits to Defendants because: (a) unlike the capsules, there were no pending ANDAs seeking approval to market generic versions of this tablet formulation at this time; and (b) TriCor B had different dosage amounts (54mg and 160mg) than the TriCor A capsules for which the generics had already developed AB-rated generic versions. Defendants purposefully developed their "new" version of TriCor with a different dosage form and different dosage strengths than the pre-existing capsules, so that the generic capsules, when approved, would not be AB-rated to (i.e. automatically substitutable for) the TriCor B tablets.

81. Defendants then stopped all new sales of TriCor A, and directed their sales force to sell only TriCor B in the future, and to pressure doctors not to write prescriptions for TriCor A. Through this tactic, Defendants intended that, by the time that generic capsules hit the marketplace, all physicians would be writing prescriptions only for TriCor B, instead of TriCor A. Since generic capsules would only be AB-rated to TriCor A, and would not be AB-rated to (and thus readily substitutable for) TriCor B, Defendants conversion of the market to TriCor B before generic entry significantly limited the inroads that generic capsules could make in the fenofibrate market.

82. Defendants also made a market-wide announcement that beginning October 2001, Defendants would no longer sell TriCor A at all. Defendants knew that a typical retail pharmacy maintains on hand only a 30-60 day supply of most pharmaceutical products. By refusing to sell TriCor A after October 2001, Defendants ensured that by January 2002--months before the expected entry of generic versions of the capsules --retail pharmacies would no longer have any branded TriCor A in their inventories.

83. Defendants' draining of TriCor A from the distribution channel had an anticompetitive purpose and effect. As a result of Defendants' draining, there was little or no TriCor A available in the marketplace from January 2002 until mid-April 2002 (when Teva entered). As a matter of good pharmacy practice and continuance of patient care, a pharmacist receiving a prescription for TriCor A during this time would call the prescribing physician to ask for permission to switch the prescription to the next closest available product, namely the TriCor B tablets.

84. Defendants' channel-draining strategy was especially effective at defeating generic substitution because TriCor is a "maintenance medication", i.e., a medication taken for a long period of time for a chronic condition. Prescriptions for TriCor are typically written for a 30-day supply with a number of refills (as many as 12) permitted. Had Defendants not drained the channel of TriCor A, in the period from January 2002 to April 2002 pharmacists could have continued to fill existing, refillable TriCor capsule prescriptions with branded TriCor A. Then, when Teva's generic product became available in April 2002, pharmacists could have satisfied the remaining refills with generic fenofibrate capsules. Defendants' channel-draining tactic prevented Teva from making these refill sales and thereby gaining a foothold for the generic in the market.

85. However, there still existed the possibility that pharmacists receiving a new TriCor B prescription would call the physician to ask permission to dispense generic fenofibrate capsules (generic TriCor A). It is the policy of most retail pharmacies to dispense generic pharmaceuticals whenever possible. Defendants were aware of this policy, however, and took additional exclusionary action to thwart even this possibility of generic competition:

a. More than 75% of all prescriptions are dispensed to patients whose medicines are paid for by a third-party plan (an insurer, HMO, Medicaid, etc.). For large retail drugstore chains, the percentage of third-party prescriptions is even higher-in excess of 90%.

b. Most third-party plans subscribe to a data service provided by First Data Bank, which indicates whether a particular drug is a branded drug or a generic drug. Third-party plans use that information to set co-payment levels for their consumers - higher co-payments for branded drugs and lower co-payments for generic drugs.

c. In or about December 2001, Defendants caused First Data Bank to list as "obsolete" the TriCor A product code in its National Drug Data File ("NDDF").

d. Under the policy followed by First Data Bank – a policy that Defendants knew that First Data Bank followed – a listing of TriCor A as "obsolete" resulted in First Data Bank identifying Teva's fenofibrate as a branded pharmaceutical product rather than a generic product. Defendants thereby caused third-party plans to require their customers to pay the higher co-payments (required for receipt of branded pharmaceuticals) in order to receive Teva's fenofibrate.

e. The practice of many retail pharmacists is that they will not call a physician to ask for permission to switch a prescription, even if the pharmacy would benefit financially, unless the patient would also save money. Moreover, very few, if any, patients would agree to a switch from TriCor B to TriCor A unless they would save money. Defendants' causing the listing of TriCor A as obsolete in the NDDF, and thus causing Teva's product to be listed as a branded drug with a high co-payment, effectively precluded any pharmacy-initiated switching of prescriptions from TriCor B to generic fenofibrate capsules. This was not by accident – Defendants were well aware of the

relationship between the NDDF and retail pharmacy distribution practice.

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86. To the extent that Defendants seek to justify these acts by claiming a desire to introduce supposedly better or superior product, this justification rings hollow because the TriCor B tablets provide no material benefits to consumers that the capsules did not already provide. Moreover, even if the tablets had some benefit over the capsules (which they did not), such benefit could have been offered without eliminating demand for TriCor A and/or reclassifying the TriCor A code in the NDDF. Had Defendants not acted to destroy the demand for TriCor A, doctors and patients would have more readily been able to weigh the relative benefits (and prices) of capsules versus tablets, and pick the formulation they preferred. However, since, in reality, Defendants' true goal was to interfere with and impede, to the greatest extent possible, generic competition, the existence of any ongoing sale of generic fenofibrate would undermine Defendants' scheme.

87. Furthermore, Defendants' scheme included taking various steps to try to create the false appearance that TriCor B was superior to the pre-existing TriCor A. Specifically, in connection with their TriCor B NDA, Defendants sought approval for an indication for TriCor B for "raising HDL-C levels in adult patients with Frederickson Types IIa and IIb dyslipidemia." In doing so, however, defendants relied upon the same clinical studies that had been submitted in support of their NDA for TriCor A. Thus, the studies submitted to obtain FDA approval for this new indication had been performed with the capsule formulations, not the tablet formulation. As the FDA Medical Officer reviewing Abbott's TriCor B NDA noted, "[t]hese studies, however, were conducted with

the standard and micronized formulation of fenofibrate. Therefore, the approvability of this application relied on the demonstrated bioequivalence between the tablet and older formulations of fenofibrate." Medical Officer's Review of New Drug Application, August 30, 2000 (Mary H. Parks, M.D., Medical Officer)(available at http://www.fda.gov/cder/foi/nda/2001/21-203_Tricor_medr.pdf).

88. Despite the fact that the clinical studies supporting this "new" indication were available at the time Defendants submitted their capsule NDA, Defendants did not seek approval for the indication of raising HDL-C levels for TriCor A, but instead waited to use the capsule clinical studies to get approval for this indication in connection with their TriCor B tablet product. The purpose and effect of this aspect of Defendants' scheme was to (a) intentionally and unfairly degrade Tricor A (and generic versions thereof) in relation to Tricor B; (b) create the false impression that Tricor B had significant medical benefits that were not provided by TriCor A; and (c) impede the ability of TriCor A to compete with the TriCor B. Defendants exploited this illusory differentiation between TriCor B and TriCor A in their marketing efforts.

89. Defendants invested significant resources in developing the TriCor B tablets. Then, Defendants invested significant resources in demonstrating to the FDA that TriCor B tablets are bioequivalent to the already-approved TriCor A formulation. Thus, in obtaining approval for TriCor B, Abbott established that the bioavailability of the two products did not differ significantly when the two products are given in similar dosages under similar conditions. After all of the expenses of researching and developing the TriCor B tablets, of submitting an NDA to the FDA in November 1999 and of supporting that application with multiple submissions to the FDA through September

2000, Defendants merely succeeded in getting approval for products that were deemed equivalent to products Defendants already had on the market.

90. Moreover, Defendants undertook the significant additional expenses of converting their manufacturing process to the TriCor B formulation. Defendants also undertook the significant additional expenses of "detailing" doctors and marketing the tablet formulation to health care entities with the goal of switching prescriptions and prescribing habits from the capsule products to the bioequivalent tablet products, which defendants brought to the market at the same price as the capsule products.

91. Since Defendants were already marketing products bioequivalent to TriCor B, the process of developing, approving, launching, and converting the demand to TriCor B by taking sales from TriCor A, would not likely have been anticipated to result in sufficient additional revenue to justify the significant associated expenses absent the anti-competitive impact on potential generic competition. Absent the expected harm to generic competition resulting from introduction of TriCor B, Defendants would not have brought that product to market.

92. The purpose and effect of Defendants' strategy was to foreclose (and/or severely limit) generic competition that otherwise would have existed in sales of fenofibrate capsules. By engaging in this "litigation and switch" scheme, Abbott and Fournier did not simply delay sales of generic fenofibrate capsules; they took additional steps that had the purpose and effect of impeding those generic capsules from ever meaningfully competing with TriCor products, even once Impax and Teva were legally permitted to begin sales, by destroying any demand for fenofibrate capsules before Teva or Impax could enter the market.

93. Moreover, there can be no doubt that the purpose and effect of Defendants' conversion strategy was to protect Defendants' monopoly power in the fenofibrate market from the threat of generic competition. For example, in an internal document reviewing the successful "Life Cycle Management" of the TriCor brand, Defendant Abbott notes that TriCor sales were expected to surpass $730 million in 2004, and that:

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94. Teva eventually overcame the automatic stay resulting from Defendants' meritless patent litigation, and entered the market with certain dosage strengths of its generic TriCor A capsules in or around April 2002. As discussed above, however, by that time Defendants' exclusionary tactics had ensured that few, if any, new prescriptions were being written for TriCor A and that, through the channel-draining strategy, even refillable TriCor A prescriptions had been switched to TriCor B.

95. Thus, as a direct and proximate result of Defendants' overall scheme to restrain trade and monopolize the fenofibrate market, Defendants effectively destroyed generic competition that

should have started in early 2002, and have improperly maintained a 95% share of the market for fenofibrate products that would have eroded substantially in the face of price competition from lower-cost generic products but for their anticompetitive conduct.

2. The Second Exclusionary Conversion

96. Having successfully preserved their blockbuster product (and monopoly profits) from generic encroachment, Defendants were quick to return to the same strategy when generic competitors again threatened to enter the fenofibrate market. This time, before this Court, Defendants executed their scheme by reflexively filing patent suits against generic competitors, regardless of the merit (or lack thereof) of such suits, in order to obtain the benefit of Hatch-Waxman 30-month stays, while using the delay occasioned by these suits to convert demand in the fenofibrate market from their original tablet formulation to a new tablet formulation. Once again, this tactic precluded generic manufacturers, who had reacted to the first conversion by developing a generic version of the original tablets, from successfully competing in the fenofibrate market.

(a). The Delaware Patent Litigation

97. In an apparent reaction to Defendants' successful conversion of the fenofibrate market to TriCor B, on or around June 17, 2002, Teva filed with the FDA an ANDA for its generic fenofibrate 54 mg and 160 mg tablets (the "Teva Tablet ANDA"), along with a Paragraph IV certification that the ANDA did not infringe the '726 patent, as well as two additional patents that Defendants had subsequently listed in the Orange Book as covering the TriCor tablets, U.S. Patent No. 6,074,670 (the "'670 patent"), which issued on June 13, 2000, and U.S. Patent No. 6,277,405 (the "'405 Patent"), which issued on August 21, 2001. On or around August 21, 2002, Teva gave

notice to Defendants of the filing of the Teva Tablet ANDA and the Paragraph IV certifications made therein. Abbott received notice of Teva's initial ANDA filing on August 26, 2002.

98. Teva subsequently amended its ANDA, on July 29, 2003 and December 17, 2003, respectively, by filing two additional Paragraph IV certifications, one for U.S. Patent 6,589,552 (the "'552 patent") and one for U.S. Patent 6,652,881 (the "'881 patent"), shortly after Abbott listed each of these patents in the Orange Book as claiming TriCor. Teva duly served Abbott with notice of each of its certifications, which prompted additional infringement complaints filed within 45 days of this notice.

99. In three separate complaints filed in the United States District Court for the District of Delaware (later consolidated into a single action), Abbott alleged that Teva had infringed the five patents to which Teva had filed Paragraph IV certifications. The first complaint, filed on October 4, 2002, alleged infringement of the '726 Patent, the '670 patent, and the '405 patent; the second complaint was filed on August 29, 2003, alleging infringement of the '552 patent; and the third complaint was filed January 22, 2004, alleging infringement of the '881 patent.

100. By virtue of the filing of the first and second complaints, Defendants imposed two successive 30-months stays under Hatch-Waxman, thus barring FDA approval of Teva's ANDA. The first 30-month stay was triggered by the first complaint filed (involving the '726, '670 and '405 patents), and it expired on February 26, 2005, 30 months after Abbott received Teva's first notice letter. The second 30-month stay was generated by the second complaint filed involving the '552 patent, and is set to expire in February 2006. Because of the modifications to Hatch-Waxman made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which prohibited

the abusive practice by Abbott and others of making successive Orange Book listings (and filing successive patent suits) in order to obtain successive 30 month stays, Abbott was not entitled to a third stay based on the third complaint for infringement of the '881 patent.

101. Similarly, Impax also sought to enter the fenofibrate market in the United States by filing an ANDA for fenofibrate tablets in or around December 2002. In connection with this ANDA, Impax submitted Paragraph IV certifications that the ANDA did not infringe the '726, the '670 and the '405 patents. As they had against Teva, Defendants sued Impax, asserting infringement of the '670 and the '405 patents. The filing of the initial infringement case, on January 23, 2003, triggered an automatic 30-month stay of approval of Impax's Tablet ANDA by the FDA. The issuance and Orange Book listing of the '552 patent resulted in an additional infringement case against Impax, and an additional 30 month stay. The listing of the '881 patent resulted in yet another suit against Impax, but again, as in the case of the suits against Teva, there was no additional 30-month stay associated with that infringement suit.

102. On March 5, 2004, the FDA granted tentative approval to Impax's and Teva's tablet ANDAs, which means that the FDA has determined that these generic products are bioequivalent to TriCor tablets of the same dosage strength, and that Teva and Impax have satisfied other regulatory requirements, such as demonstrating safety and efficacy, for sale of their fenofibrate product in the United States. The tentative approvals by the FDA would have been final approvals but for the successive 30-month stays resulting automatically from Abbott's and Fournier's filing and maintenance of their patent infringement actions against Impax and Teva concerning the tablet ANDAs, because the FDA was legally precluded from granting final approval to Impax or Teva,

until the stays expire or until the various Delaware infringement actions were resolved in favor of the generic manufacturers. Notably, both Teva and Impax have represented to this Court that, absent the 30-month stays, they would have received final approval on March 5, 2004, and would have entered the market shortly thereafter.

103. The various infringement suits in Delaware against Teva and Impax were consolidated and/or coordinated before this Court (the "Delaware Patent Litigation"). The Delaware Patent Litigation was heavily litigated by and among Defendants, Teva and Impax, and trial was scheduled to begin on December 6, 2004. Defendants succeeded in getting this trial date pushed back six months, however, until June 6, 2005, through the filing of the subsequent infringement actions related to the '552 patent. Then, with less than a month to go before trial, Abbott and Fournier (having obtained the sought-after delay from the litigation and having already used that delay to thwart generic competition by successfully converting the fenofibrate market to Defendants' new tablet formulation), sought voluntary dismissal of all the pending Delaware infringement actions.

(b). Defendants Execute The Second Market Switch

104. Defendants' abandonment of the Delaware Patent Litigation reveals their true motive for commencing these actions in the first place – to again provide Defendants cover to convert the existing multi-million dollar fenofibrate market to a formulation not threatened by generic competition. During the pendency of the Delaware Patent Litigation, Abbott and Fournier were planning another product switch, which was implemented in late 2004, more than eight months after the generic manufacturers received tentative approval from the FDA for their tablet ANDAs.

(1). Defendants Revisit and Refine The Market Conversion Strategy

105. As shown by Defendants' own documents, quoted above, the continued economic success of the TriCor cash cow was directly attributable to the success of the first market conversion, from TriCor A to TriCor B. Yet Defendants realized that the exclusionary effect of their first market conversion was not permanent.

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To account for this weakness, Defendants developed (or, in TriCor's case, repeated) the strategy that had worked before:

Redacted

[1] This "practical market exclusivity" referred to (1) the time it would take for generic manufacturers to develop, file and receive FDA approval for an ANDA embodying AB-rated generic versions of Defendants' original tablet formulation (forecast internally to be approximately 24 months); plus (2) the stay of up to 30 months that Defendants would obtain by merely filing patent suits regarding Defendants late listed patents, whether or not those suits had any merit.

106. The stated goal of the second conversion, just as with the first conversion, was "to convert over 95% of the fenofibrate business to the new Tricor . . . within 6 months," so that the

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[1] **Redacted** Plaintiffs believe that Defendants are planning yet another exclusionary market conversion at this time. However, due to Defendants' heavy redactions of the documents produced to date –purportedly relating to Defendants' future plans regarding fenofibrate –Plaintiffs are unable to make detailed allegations regarding those future plans. Plaintiffs believe Defendants' redactions are improper, and will challenged them in due course.

market would be converted to a second tablet formulation (TriCor C) before generic versions of TriCor B received FDA approval. The second conversion was executed with a series of steps similar to those Defendants used in the first conversion.

107. First, under cover of the delay in generic entry caused by the first conversion, as well as the Delaware Patent Litigation, Defendants developed TriCor C. Defendants obtained FDA approval for the NDA for TriCor C (in 48mg and 145 mg strengths) on November 5, 2004. TriCor C includes the same medicine, and is indicated for the same uses, as the TriCor B tablet formulation. However, by virtue of its new dosage strengths, TriCor C would not be susceptible to substitution from generic versions of TriCor B.

108. Like TriCor B in the first conversion, TriCor C provided no significant medical or clinical benefits to consumers that were not provided by the TriCor B tablet formulation, a fact that was acknowledged in the marketplace.

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Moreover, Abbott's research concluded that "health plans are suspect of new product formulations," and "plans do not perceive the [TriCor C] formulation as a clinical innovation, or a significant benefit."

109. While TriCor C did allow patients the convenience of taking TriCor without meals, these tablets did not provide any medical or clinical benefits that were not already provided by either TriCor A or TriCor B.

110. TriCor C tablets included nanotechnology developed by Elan Corporation, Plc. ("Elan") and licensed to Defendants. Defendants' purpose and effect in obtaining this license was not to significantly improve TriCor, but rather was to impede or minimize generic substitution by: (a) switching the fenofibrate market to a product that was not AB-rated to the existing TriCor B tablet formulation, and (b) make it more difficult and time-consuming for manufacturers to develop generic versions of the new TriCor C tablets.

111. Moreover, on information and belief, **Redacted**, the license Defendants obtained from Elan was an exclusive license, precluding Elan from licensing its nanotechnology to any other manufacturer of a fenofibrate compound. This act was itself anticompetitive.

112. Having obtained FDA approval for TriCor C while the 30-month stays from the Delaware Patent Litigation were still in effect, Defendants repeated all the exclusionary conduct in which they had engaged in connection with the conversion from TriCor A to TriCor B:

a. Defendants directed Abbott's detailers to market only TriCor C to the exclusion of TriCor B, and to urge physicians not to write prescriptions for TriCor B;

b. Defendants stopped selling TriCor B altogether and drained the distribution channel of those tablets so that pharmacists presented with a prescription for TriCor B would call the physician to request a switch to the new tablets. Apparently unsatisfied with their prior efforts to drain the distribution channel of TriCor A, Defendants intensified those efforts in connection with draining the channel of TriCor B. This intensified tactic involved a modification of Abbott's policy regarding returned goods: Under Abbott's standard returned-goods policy, wholesalers and retailers do not receive a refund based on the amount of unsold product actually returned to Abbott. Instead, Abbott simply provides a 1% returned-goods allowance at the time of purchase. As part of their scheme to drain all TriCor B from the distribution channel, however, Defendants changed the returned-goods policy with respect to those tablets. In or about March 2005, Defendants announced that all unsold TriCor B tablets could be returned, regardless of quantity, for a refund in the amount of the full purchase price (less certain discounts and the 1% allowance). This exclusionary tactic was intended to ensure that the distribution channel would be drained of TriCor B tablets before the generic competitors could enter the market.

c. Defendants caused First Data Bank to list the TriCor B tablet product as obsolete in the NDDF, with the purpose and effect of causing third-party plans to no longer cover branded TriCor B and of causing plans to charge their customers the higher, branded co-payment for Teva's or Impax's 54mg and 160mg generic fenofibrate tablet products.

113. Defendants' second conversion was intended to prevent, and likely will prevent, new prescriptions for TriCor B from being written, and will encourage current prescriptions for TriCor B to be converted to the replacement TriCor C. In the future, this will mean that a pharmacist will

not be presented with a prescription that would allow for substitution with a cheaper generic version of TriCor B, should one become available.

(2). As With the First Conversion, the Purpose and Intent of the Second Conversion Was to Illegally Maintain Defendants' Monopoly Power in the Fenofibrate Market

114. As alleged above, but for Abbott's and Fournier's anticompetitive conduct, the tablet formulations (TriCor B and C) likely never would have been introduced (because generic capsules would have dominated the market, and the tablets offered no material benefits over the capsules). In the alternative, however, if Defendants would have introduced the TriCor B tablets absent the anticompetitive conduct, the generic manufacturers would have started selling their generic fenofibrate 54 mg and 160 mg tablets shortly after March 5, 2004, the date on which FDA granted tentative approval (and but for Abbott and Fournier's conduct would have granted final approval) to Impax's and Teva's tablet ANDAs. Abbott and Fournier only received approval for their TriCor C NDA in November of 2004, so they could not have started their efforts to switch the market until that time. Thus, but for Abbott's and Fournier's conduct, Impax and Teva would have started selling their fenofibrate tablets more than roughly eight months before Abbott and Fournier could have started converting the market to their new TriCor C formulation.

115. Had Teva and Impax been able to start selling their generic versions of TriCor B tablets in March of 2004, the generic manufacturers would have successfully entered the fenofibrate market and would have captured significant sales. Impax and Teva also would be able to maintain demand for the TriCor B tablets even if Abbott and Fournier were to remove the reference for TriCor B tablets from the NDDF after the generics were already on the market. This is because, if a generic

fenofibrate formulation is available on the market before Abbott and Fournier are able to complete the switch, there would continue to be pressure from the managed care industry for patients to continue to be prescribed the TriCor B tablets. If, however, a generic product does not get to market before the switch is completed, the managed care industry will not exert pressure to return patients to the generic TriCor B tablets once those products become available. By taking actions that have postponed the launch date for Teva's and Impax's TriCor B tablets, Defendants have again barred Teva and Impax from availing themselves of the most efficient and practical means of distributing their generic drug products, again effectively preserving the fenofibrate market solely for the benefit of Defendants' monopoly profits.

116. As the MCO study quoted above demonstrates, TriCor is not the first product with which Abbott has engaged in a scheme to convert the market for a drug molecule from one dosage form to another for the specific purpose of delaying or impeding generic competition. In the Hytrin (generically, terazosin hydrochloride) conversion mentioned above, in anticipation of generic tablet entry, Abbott switched the terazosin hydrochloride market from tablets to capsules, telling its customers at that time that capsules were superior to tablets. In contrast, in connection with the first Tricor conversion, Abbott switched the market from capsules to tablets, purportedly because tablets were superior to capsules. On information and belief, Abbott engaged in other market conversions for the express purpose of thwarting generic competition, with the drug product Tranxene, and possibly other products.

117. Abbott's past conduct in excluding generic competition through market conversions corroborates Plaintiffs' allegations here that the TriCor conversions were likewise committed

knowingly and with the intent of improperly excluding or impeding generic competition, and therefore improperly maintaining Abbott's monopoly in the fenofibrate market.

3. Defendants' Improper Litigation Conduct and Inequitable Conduct Before the PTO in Support of Their Overarching Scheme

118. In support of the overarching scheme alleged herein, Defendants: (a) filed and maintained sham patent litigation; (b) improperly filed and maintained patent litigation without a reasonable basis, and with indifference as to whether or not the suits had merit; and (c) committed inequitable conduct before the PTO in order to obtain patents that could later be used to delay generic competition.

119. All of the Illinois Patent Litigation, and a substantial portion of the Delaware Patent Litigation filed by Defendants, were both objectively and subjectively a sham.

(a). The Sham '726 Patent Suits

120. In the Illinois Patent Litigation, Abbott and Fournier alleged that Teva's and Impax's proposed generic versions of TriCor capsules infringed Fournier's '726 patent. This allegation of patent infringement was objectively baseless, and Defendants knew it was objectively baseless. The Illinois Patent Litigation was brought not because Defendants believed they had a realistic chance of prevailing in the litigation, but rather because by filing the litigation, regardless of its outcome, Defendants were able to delay generic competition for up to 30 months.

121. As explained earlier, the claims, specification, original prosecution history and reexamination prosecution history of the '726 patent made it absolutely clear that the patent is limited to a fenofibrate formulation in which co-micronization is performed on a mixture of fenofibrate and a solid surfactant without the presence of additional excipients. As Defendants were aware from

Novopharm's paragraph IV certification, Teva's proposed generic capsule was not made using co-micronization. Instead, under Teva's process, fenofibrate was first pre-micronized on its own and in the absence of any other ingredient. The pre-micronized fenofibrate was then dry mixed with lactose monohydrate, pregelatinized starch, croscarmellose sodium and crossprovidone. After some additional steps, including wet granulation and drying, the dried, granulated mixture was then dry blended with additional excipients to produce granules that can pass through a #16 mesh screen. The granulated mixture was then blended again, weighed and stored for eventual encapsulation into gelatin capsules. Impax's proposed generic capsule was made using a similar process.

122. Since it was obvious that the '726 patent claims were limited to a formulation in which fenofibrate and a solid surfactant are co-micronized in the absence of other excipients, and equally obvious that Teva's and Impax's proposed products were not made using such a process, no reasonable litigant could have realistically expected to prove infringement against either generic applicant under 35 U.S.C. § 271(e)(2)(A). In fact, neither Abbott nor Fournier expected to do so. Abbott and Fournier knew that it was only a matter of time before their claim was defeated, but time was exactly what they were seeking. Abbott and Fournier needed to delay approval of Teva's and Impax's ANDAs long enough for them to convert the market to the original TriCor tablets, and the Illinois Patent Litigation gave them sufficient time to do so.

123. As noted above, the Illinois district court granted summary judgment to Teva in the Illinois Patent Litigation in March 2002, finding that the '726 patent claims had to be construed in the manner described in the patent and that, so construed, Teva's proposed generic capsule did not infringe any of those claims. The district court had no difficulty in reaching this conclusion. The

trial court's ruling was affirmed only a year later by the United States Court of Appeals for the Federal Circuit, which likewise had no difficulty in rejecting Defendants' position. As the Federal Circuit pointed out in its opinion, the specification of the patent and other circumstances made it "abundantly clear that 'co-micronization of . . . fenofibrate and a solid surfactant' should be construed as referring to co-micronization of a mixture consisting essentially of fenofibrate and solid surfactant." *Abbott Laboratories v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003).

124. Even after their defeat in the action against Teva, Defendants continued to press the same infringement allegations against Impax. When Impax argued that Defendants were collaterally estopped by the claim construction ruling issued by the district court in the prior litigation against Teva, Defendants made the frivolous arguments that collateral estoppel did not apply because (1) "a district court is not bound by another court's claim construction;" (2) the district judge in the prior action "misunderstood the pharmaceutical technology and issues in the '726 patent;" and (3) the ruling was on appeal. *See Abbott Laboratories v. Impax Laboratories, Inc.*, 2003 WL 1563426, *4-5 & n.4 (N.D. Ill. 2003). Each of these arguments was contrary to controlling Supreme Court or Federal Circuit precedent, and each was easily rejected by the Illinois district court.

125. Moreover, in the Delaware Patent Litigation, Defendants reasserted their claims that Teva and Impax infringed the '726 Patent, despite the fact that, (a) the claim was frivolous when it was first made in the Illinois Patent Litigation; and (b) the Illinois district court had already rejected this claim emphatically.

(b). Defendants File Patent Suits Without Basis, And With Complete Indifference to Whether the Suits Have Merit

126. Defendants alleged in the Delaware litigation that Teva's proposed generic version of TriCor B infringed the '726, '670, '405, '552 and '881 patents. Defendants had no factual basis for such allegations at the time they were made. Defendants had performed no tests of any kind on the Teva product before alleging infringement, despite the fact that Teva had provided samples of its product to Defendants. Defendants made no effort to determine whether or not there was infringement before filing suit. Defendants did not conduct any tests on any unexpired Teva fenofibrate tablets until May of 2005, almost three years after they had filed the first of the Delaware patent cases.

127. In connection with each of the paragraph IV certifications made by Teva, Teva was required to and did provide Defendants with a detailed statement explaining why Teva's proposed generic products did not infringe any of Defendants' patents. Teva also provided Defendants with technical material from its ANDA demonstrating the lack of infringement.

128. In fact, Defendants did not file the Delaware Patent Litigation because they believed they had a chance of prevailing in the litigation or because they genuinely desired to prevail. Defendants filed the Delaware Patent Litigation solely because, merely by filing those cases, they were able to trigger a regulatory delay of up to 30 months in FDA approval of Teva's ANDA.

(c). Inequitable Conduct

129. Defendants were guilty of inequitable conduct in obtaining the '881 patent, and Defendants knew they were guilty of inequitable conduct. Inequitable conduct renders a patent unenforceable.

130. The '881 patent resulted from Application No. 10/288,425, filed November 6, 2002. The '881 patent is owned by Fournier. According to the '881 patent, the poor solubility of fenofibrate interferes with its bioavailability, causing bioavailability to be "incomplete." The '881 patent asserts that there is a need to improve fenofibrate bioavailability by achieving a dissolution that is "close to 100% over very short periods of time."

131. The '726 patent, also owned by Fournier, describes a fenofibrate formulation that is prior art to the '881 patent. The '726 patent also discloses a method of improving fenofibrate solubility, and thus bioavailability, by co-micronizing fenofibrate with a solid surfactant. Lipanthyl 200M, a fenofibrate pharmaceutical product sold by Fournier in Europe, is an embodiment of the '726 patent and is the same formulation as TriCor capsules.

132. The '881 patent defines the requirements for dissolution as greater than 10% in five minutes, 20% in ten minutes, 50% in 20 minutes and 75% in 30 minutes in a medium comprised of 1200 ml water to which 2% Polysorbate 80 is added, or of 1000 ml of water to which 0.025 M sodium lauryl sulfate is added, with a blade rotation speed of 75 rpm. The patent asserts that these higher dissolution requirements are met "by a new method for preparing a pharmaceutical composite by spraying a suspension of the active ingredient onto an inert hydrosoluble carrier."

133. During the prosecution of the application that led to the '881 patent, the Examiner rejected prosecution claims 1-14 and 22-41 as obvious over the '726 patent. In response to this rejection, Fournier distinguished the '726 patent by its dissolution profile, arguing that the invention being claimed "has an unexpectedly superior dissolution profile" compared to the prior art disclosed in the '726 patent.

134. The Examiner allowed the claims, finding that the '726 patent failed to teach a composition having a dissolution of at least 10% in five minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes. According to the Examiner's Statement of Reasons for Allowance, the "instant invention [claimed in the '881 patent] has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M (as taught by [the '726 patent])." Thus, the dissolution profile of Lipanthyl 200M was material to the allowance of the claims in the '881 patent.

135. Philippe Reginault is a named inventor of the '726 patent. He served as Fournier's director of pharmaceutical development in charge of formulation, scale up and analytical development from 1988 to 2002. Beginning in 2002, Reginault served as Fournier's director of pharmaceutical technologies evaluation.

136. Reginault conducted tests and submitted declarations to the PTO during the prosecution of the application that led to the '881 patent. These declarations falsely represented to the PTO that the dissolution rates of prior-art fenofibrate compositions were lower than they actually were, and failed to disclose results showing dissolution rates for such compositions that were higher than those provided to the PTO. Reginault did not provide test results relating to Lipanthyl 200M, the formulation cited in the Examiner's Statement of Reasons for Allowance, although Reginault had such results in his possession and such results were material.

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139. Reginault did not disclose dissolution data for Lipanthyl 200M that were much better than those submitted to the PTO in the patent application that led to the '881 patent.

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141. In addition to better dissolution test results, Reginault failed to disclose that the dissolution results for the capsule embodiments of the prior art provided to the PTO may have been lower than the actual dissolution of the active ingredient because of hardening of the capsule gelatin during storage.

142. The information not disclosed by Reginault was highly material to the patentability of the claimed invention.

143. Reginault was aware of the duty to disclose material information when providing submissions to the PTO during the prosecution of a patent application and acknowledged that duty.

144. The information withheld by Reginault was withheld with an intent to deceive the Patent Examiner.

145. In listing and enforcing the '881 patent, Defendants sought to enforce a patent they knew to be unenforceable. Since the facts evidencing their inequitable conduct were certain to come

out during the litigation, Defendants' effort to enforce the patent was doomed to fail. In fact, no reasonable litigant could have realistically expected to prevail in the case.

146. Defendants brought the '881 patent litigation pursuant to a policy of filing patent infringement actions without regard to their merit and solely for the purpose of delaying generic entry.

E. Effect on Interstate Commerce

147. At all material times, TriCor, manufactured and sold by Defendants, was shipped across state lines and sold to customers located outside its state of manufacture.

148. During the relevant time period, in connection with the purchase and sale of TriCor, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

149. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

F. Monopoly Power

150. Through the anticompetitive conduct alleged herein, Defendants were able to charge supracompetitive prices for fenofibrate, and thus, by definition, maintained market power and/or monopoly power with respect to fenofibrate sold in the United States. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is all fenofibrate products – i.e., TriCor (in

all its forms and dosage strengths), and bioequivalent fenofibrate products. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which fenofibrate is prescribed. For the entire period relevant to this case, Defendants have been able to profitably maintain the price of their branded fenofibrate products well above competitive levels.

151. The relevant geographic market is the United States and its territories.

152. Defendants' market share in the relevant market is and was 100% at all times prior to the sale of Teva's fenofibrate capsules in the United States, and has been at least 95% thereafter.

153. Defendants' actions are part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

154. Defendants' illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of TriCor resulted in Plaintiffs and the Class paying more than they would have paid for fenofibrate, absent Defendants' illegal conduct.

G. Effects on Competition and Damages to Plaintiffs and Class

155. Defendants' exclusionary conduct has delayed or prevented the sale of generic fenofibrate in the United States, and unlawfully enabled Defendants to sell TriCor at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of TriCor A by at least April 9, 2002, if not earlier, and additional generic competitors would have entered the market thereafter. Moreover, to the extent that demand for TriCor B would have existed but for Defendants' illegal conduct, generic competitors

would have begun marketing generic TriCor B tablets by at least March 5, 2004, and additional generic competitors would have entered the market thereafter.

156. Defendants' pattern and practice of delaying generic entry while simultaneously changing product formulations and discontinuing existing products and delisting the drug from the NDDF, as alleged above, is exclusionary and unreasonably restrains competition. To the extent that Abbott and Fournier have any valid business purpose for their conduct, that purpose could be served by means that are less restrictive of competition, and would at all events be outweighed by the anticompetitive effects of the conduct. Among other things, Abbott and Fournier could have launched a new tablet product without taking affirmative steps to destroy the demand for the existing capsule product. Abbott's and Fournier's conduct has allowed, and continues to allow, them to maintain a monopoly and exclude competition in the relevant market, to the detriment of all fenofibrate purchasers, including Plaintiffs, members of the Class, and consumers. Accordingly, the anticompetitive effects of Defendants' conduct clearly outweigh the purported procompetitive benefits (if any) of such conduct.

157. Similarly, Defendants cannot justify their conduct with any supposed consumer benefit, as the enormous cost savings offered by generic drugs outweigh any supposed benefit from the new formulations of TriCor, which benefits are illusory and/or could have been obtained without taking affirmative steps to destroy demand for fenofibrate capsules. Defendants' exclusionary motive is also illustrated by their willingness to sacrifice profits as part of the market switch strategy: Defendants' decision to incur the extra costs necessary to change formulations was economically rational only if the change has the effect of excluding generic competition. Defendants' introduction

of TriCor B, which was bioequivalent to TriCor A, and which relied upon the same clinical studies as were used to support the TriCor A NDA, was itself anti-competitive. But for the impact on generic competition, Defendants would not have invested the resources necessary to bring the TriCor B tablets to the market. But for the impact on generic competition, it would not have been economically rational to invest in the process of developing the bioequivalent tablet formulation, seeking FDA approval of that formulation, changing the manufacturing process, and engaging in significant marketing efforts to switch the market from capsules to the equivalently priced tablets.

158. If manufacturers of generic fenofibrate had been able to enter the marketplace and effectively compete with Defendants earlier, as set forth above, Plaintiffs and other members of the Class would have substituted lower-priced generic fenofibrate for the higher-priced brand-name TriCor for some or all of their fenofibrate requirements, and/or would have paid lower prices for some or all of their remaining TriCor purchases.

159. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of TriCor directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their fenofibrate requirements. Plaintiffs and the other Class members paid prices for fenofibrate that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic fenofibrate instead of expensive brand-name TriCor; (2) Class members paid artificially inflated prices for generic fenofibrate and/or (3) the price of branded TriCor was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs

and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

COUNT I
Monopolization in Violation of Section 2 of the Sherman Act:
Defendants Delayed And Excluded Competition Through An Overarching Scheme

160. Plaintiffs refer to, and incorporate herein, the allegations above in ¶¶ 1– 159.

161. At all relevant times, Defendants possessed monopoly power in the relevant market.

162. Defendant Fournier manufactured the various formulations of TriCor described herein, and licensed the various patents related to TriCor to Defendant Abbott. Abbott, inter alia, marketed and sold those various versions of TriCor in the United States. Abbott and Fournier divided the costs of, and revenues and profits from, TriCor between themselves.

163. Abbott and Fournier worked closely and in concert throughout the overarching scheme alleged herein to maintain their monopoly power in the fenofibrate market. Abbott and Fournier, singularly and jointly, each actively participated in all or most of the components of the exclusionary scheme described below, and each benefitted (and continue to benefit) from the scheme as alleged herein. Each acted in furtherance of the exclusionary scheme with the knowledge, assistance and/or acquiescence of the other.

164. During the relevant period, Defendants willfully and unlawfully maintained their monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants engaged in an exclusionary scheme that included, inter alia, each of the following (at various times):

a. modifying TriCor A to TriCor B;

b. directing Abbott's detailers to market only TriCor B and to urge physicians not to write prescriptions for TriCor A;

c. withdrawing TriCor A from the market and draining the distribution channel of TriCor A;

d. causing First Data Bank to list TriCor A as obsolete in the NDDF;

e. modifying TriCor B to TriCor C;

f. directing Abbott's detailers to market only TriCor C and to urge physicians not to write prescriptions for TriCor B;

g. withdrawing TriCor B from the market and draining the distribution channel of TriCor B;

h. causing First Data Bank to list TriCor B as obsolete in the NDDF;

i. engaging in sham and baseless litigation, and inequitable conduct before the PTO; and

j. entering into an exclusive license with Elan.

165. The goal, purpose and/or effect of Defendants' scheme was to prevent, delay, and/or minimize the success of the entry of generic fenofibrate competitors which would have sold generic fenofibrate in the United States at prices significantly below Defendants' prices for TriCor, which would have effectively caused the average market price of fenofibrate to decline dramatically.

166. The goal, purpose and/or effect of Defendants' scheme was also to maintain and extend Defendants' monopoly power with respect to fenofibrate. Defendants' illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace

of any generic version of TriCor enabled Defendants to continue charging supra-competitive prices for fenofibrate without a substantial loss of sales.

167. As a result of Defendants' illegal scheme, Plaintiffs and the Class paid more than they would have paid for fenofibrate, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of TriCor well before they actually did, and/or would have been able to market such versions more successfully.

168. If manufacturers of generic fenofibrate had been able to enter the market and compete with Defendants in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic fenofibrate for the higher-priced brand-name TriCor for some or all of their fenofibrate requirements, and/or would have received lower prices on some or all of their remaining TriCor purchases.

169. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of TriCor directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their fenofibrate requirements. Plaintiffs and all of the other class members paid prices for fenofibrate that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic fenofibrate instead of expensive brand-name TriCor; (2) class members were forced to pay artificially inflated prices for generic fenofibrate and/or (3) the price of branded TriCor was artificially inflated by Defendants' illegal conduct.

170. Defendants' scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for fenofibrate in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

171. Defendants' violations threaten continuing loss and injury to Plaintiffs unless enjoined by this Court.

COUNT II

Monopolization in Violation of Section 1 of the Sherman Act:
Defendants Conspired to Execute the Overarching Scheme

172. Plaintiffs refer to, and incorporate herein, the allegations above in ¶¶ 1–159.

173. At all relevant times, Defendants Abbott and Fournier have been engaged in a contract, combination or conspiracy in unreasonable restraint of trade, the purpose and effect of which have been to implement a scheme to delay, impede and restrain competition in the relevant market.

174. At all relevant times, Defendants possessed market and monopoly power in the relevant market.

175. Defendant Fournier manufactured the various formulations of TriCor described herein, and licensed the various patents related to TriCor to Defendant Abbott. Abbott, inter alia, marketed and sold those various versions of TriCor in the United States. Abbott and Fournier divided the costs of, and revenues and profits from, TriCor between themselves.

176. Abbott and Fournier worked closely and in concert throughout the overarching scheme alleged herein to maintain their monopoly power in the fenofibrate market. Abbott and Fournier, singularly and jointly, each actively participated in all or most of the components of the

exclusionary scheme described below, and each benefitted (and continue to benefit) from the scheme as alleged herein. Each acted in furtherance of the exclusionary scheme with the knowledge, assistance and/or acquiescence of the other.

177. During the relevant period, Defendants agreed and conspired to willfully and unlawfully maintained their monopoly power in the fenofibrate market by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants engaged in an exclusionary scheme that included, inter alia, each of the following (at various times):

a. modifying TriCor A to TriCor B;

b. directing Abbott's detailers to market only TriCor B and to urge physicians not to write prescriptions for TriCor A;

c. withdrawing TriCor A from the market and draining the distribution channel of TriCor A;

d. causing First Data Bank to list TriCor A as obsolete in the NDDF;

e. modifying TriCor B to TriCor C;

f. directing Abbott's detailers to market only TriCor C and to urge physicians not to write prescriptions for TriCor B;

g. withdrawing TriCor B from the market and draining the distribution channel of TriCor B;

h. causing First Data Bank to list TriCor B as obsolete in the NDDF;

i. engaging in sham and baseless litigation, and inequitable conduct before the PTO; and; and

j. entering into an exclusive license with Elan.

178. The goal, purpose and/or effect of Defendants' collective conduct was to prevent, delay, and/or minimize the success of the entry of generic fenofibrate competitors which would have sold generic fenofibrate in the United States at prices significantly below Defendants' prices for TriCor, which would have effectively caused the average market price of fenofibrate to decline dramatically.

179. The goal, purpose and/or effect of Defendants' collective conduct was also to maintain and extend Defendants' monopoly power with respect to fenofibrate. Defendants' illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of TriCor enabled Defendants to continue charging supra-competitive prices for fenofibrate without a substantial loss of sales.

180. As a result of Defendants' illegal conspiracy in restraint of trade, Plaintiffs and the Class paid more than they would have paid for fenofibrate, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of TriCor well before they actually did, and/or would have been able to market such versions more successfully.

181. If manufacturers of generic fenofibrate had been able to enter the market and compete with Defendants in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic fenofibrate for the higher-priced brand-name TriCor for some or

all of their fenofibrate requirements, and/or would have received lower prices on some or all of their remaining TriCor purchases.

182. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of TriCor directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their fenofibrate requirements. Plaintiffs and all of the other class members paid prices for fenofibrate that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic fenofibrate instead of expensive brand-name TriCor; (2) class members were forced to pay artificially inflated prices for generic fenofibrate and/or (3) the price of branded TriCor was artificially inflated by Defendants' illegal conduct.

183. Defendants' collective conduct has had a substantially adverse effect on competition in the relevant market, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

184. Defendants' violations threaten continuing loss and injury to Plaintiffs unless enjoined by this Court.

VI. DEMAND FOR JURY

185. Plaintiff demands trial by jury on all issues so triable.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully prays that:

(i) The Court determine that this action may be maintained as a class action pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

(ii) The acts alleged herein be adjudged and decreed to be an unlawful restraint of trade in violation of Section 2 of the Sherman Act;

(iii) Each member of the Class recover three-fold the damages determined to have been sustained by each of them, and that joint and several judgment be entered against Defendant in favor of the Class;

(iv) The Court grant permanent injunctive relief which enjoins Defendants from continuing their illegal conduct, and requires them to take affirmative steps to dissipate the effects of their prior violations;

(v) The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

(vi) The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

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Dated: September 23, 2005

CERTIFICATE OF SERVICE

I hereby certify that on October 3, 2005, I electronically filed the DIRECT PURCHASER CLASS PLAINTIFFS' FIRST AMENDED AND CONSOLIDATED CLASS ACTION COMPLAINT (REDACTED VERSION), using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that on October 3, 2005 I caused a copy of the aforementioned document to be delivered to the following attorneys in the via e-mail:

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